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09/756,092	01/08/2001	Michael J. Cima	10436-0009-999	5650

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EXAMINER

EPPERSON, JON D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/756,092

Applicant(s)

CIMA ET AL.

Examiner

Jon D Epperson

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 180-304 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 180-304 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### SUPPLEMENTAL RESTRICTION

1. The Response filed July 9, 2004 is acknowledged.
2. Upon further review of Applicants' newly added claims (e.g., claims 180-304; see 7/9/2004 Response; see also 4/7/2004 Response), an additional restriction and/or election of species was deemed necessary (see below).
3. Please note that all previous restriction and/or species election requirements remain in effect.

#### *Election/Restriction*

4. Upon review of the instant case, the application was deemed to contain claims directed to patentably distinct species of the claimed invention. Election from the following species is required. Note: applicant must elect *one* species from *each* subgroup below. Claim 180 is generic

#### Subgroup 1: Species of small molecule pharmaceutical (see claims 180, 195)

Applicant must elect, for the purposes of search, a *single species* of small molecule pharmaceutical wherein a *specific structure* is set forth, which clearly shows all of the atoms and bonds that are necessary to define said small molecule pharmaceutical i.e., only **ONE** small molecule should be elected. Applicant should *not* use notations like X or R when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected (e.g., see specification, page 72, section 7.1 wherein glycine is disclosed i.e., a single molecule). Applicants must also indicate whether the elected small molecule pharmaceutical has evaded crystallization or not (e.g., see claim 195). Applicants must also indicate whether the compound is known or unknown (e.g., see claims 200 and 201).

Art Unit: 1639

Applicants must also provide the molecular weight of the small molecule pharmaceutical (e.g., see claim 228).

Subgroup 2: Species of tubes (e.g., see claim 180)

Applicant must elect, for the purposes of search, a single species of tubes (e.g., specification, page 72, line 18 wherein glass vials are disclosed). Please elect only **ONE** tube.

Subgroup 3: Species of support plates or sample well plates (e.g., see claim 180)

Applicant must elect, for the purposes of search, a single species of sample support plates or sample well plates (e.g., specification, page 72, line 18 wherein heating/cooling block is disclosed). Please elect only **ONE** type of heating/cooling block.

Subgroup 4: Species of automated dispensing apparatus (e.g., see claim 180)

Applicant must elect, for the purposes of search, a single species of automated dispensing apparatus (e.g., see specification, page 60, line 7 wherein inkjet dispenser is disclosed). Please elect **ONE** dispensing machine i.e., and inkjet printer. Applicants must also indicate whether or not said dispensing means possesses pipette tips having septum-piercing capability (e.g., see claim 187).

Subgroup 5: Species of formulation software (e.g., see claim 180)

Applicant must elect, for the purposes of search, a single species of formulation software (e.g., see specification, page 38, line 19 wherein MatLab software is disclosed).

Subgroup 6: Species of informatics (e.g., see claim 180)

Applicant must elect, for the purposes of search, a single species of informatics.

Subgroup 7: Species of analysis (e.g., see claims 180, 282)

Applicant must elect, for the purposes of search, a single species of analysis (e.g., see claim 282 wherein atomic force microscopy is disclosed). Please elect **ONE** analysis method. Please don't elect a genus that contains many methods (e.g., visual analysis).

Subgroup 8: Species of array number (e.g., see claims 180, 202)

Applicant must elect, for the purposes of search, a single species of array number (e.g., see claim 185 where array with 1000 samples is disclosed). Applicants must also indicate how many subarrays are contained within said array (e.g., see claim 202 wherein 1 subarray is disclosed).

Art Unit: 1639

Subgroup 9: Species of solvent used for all samples (e.g., see claim 180)

Applicant must elect, for the purposes of search, a single species of solvent used for all samples (e.g., see specification, page 72, last paragraph wherein acetic acid/water is used). Applicants must also indicate if the samples are grouped in order of increasing polarity.

Subgroup 10: Species of sample difference (e.g., see claim 180)

Applicant must elect, for the purposes of search, a single species of sample difference (e.g., the amount of concentration of the small molecule pharmaceutical). Please elect only ONE sample difference. In addition, all chemicals used to describe the difference must be disclosed. For example, if Applicants elect "identity of one or more of a solvent, acid or base" Applicants must further specify whether the "solvent", "acid" or "base" is different (e.g., the sample difference is the "base"). In addition, Applicants must also specify which "bases" are used e.g., succinate chloride etc. (e.g., see claim 239).

Subgroup 11: Species of method for grouping (e.g., see claim 189)

Applicant must elect, for the purposes of search, a single species of method for grouping (e.g., Raman spectroscopy).

Subgroup 12: Species of grouping (e.g., see claim 198)

Applicant must elect, for the purposes of search, a single species of grouping (e.g., see claim 198 wherein (a) containing no precipitate is disclosed).

Subgroup 13: Species of processing method (e.g., see claims 206, 207, 210, 211, etc.)

Applicant must elect, for the purposes of search, a single species of processing method (e.g., see claims 206 wherein nucleation event is disclosed). In addition, Applicants must specify all reagents used in the processing method (e.g., Applicants must specify the chemicals used in the nucleation event). Please elect only ONE representative processing method.

Subgroup 14: Species of sample amount (e.g., see claim 231)

Applicant must elect, for the purposes of search, a single species of sample amount e.g., 100 nanograms. Please ONE specific amount.

Subgroup 15: Species of sample volume (e.g., see claim 232)

Art Unit: 1639

Applicant must elect, for the purposes of search, a single species of sample volume e.g., 200 µl. Please ONE specific volume.

Subgroup 16: Species of components if present (e.g., see claims 248-254)

Applicant must elect, for the purposes of search, a single species of components if present (e.g., see specification, page 72, last paragraph wherein DL-alanine is disclosed). Applicants must further indicate elect ONE effect e.g., effect on crystal “habit”, “polymorphic form”, “promotes or controls nucleation”, etc. for said component (e.g., see claims 248-254).

Subgroup 17: Species of physical property screened (e.g., see claims 257-264)

Applicant must elect, for the purposes of search, a single species of physical property e.g., solubility. Please elect ONE physical property.

Subgroup 18: Species of structural property screened (e.g., see claim 265)

Applicant must elect, for the purposes of search, a single species of structural property screened e.g., surface to volume ratio. Please elect ONE physical property.

Subgroup 19: Species of crystalline salt form (e.g., see claim 297)

Applicant must elect, for the purposes of search, a single species of crystalline salt form e.g., clathrate. Please elect ONE species of crystalline salt form.

5. **Please Note:** Applicants must disclose which claims read on the elected species (see paragraphs 8 and 9 below).
6. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter.

Art Unit: 1639

Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

8. Applicant is advised that a reply to this requirement **must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered **nonresponsive** unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, **applicant must indicate which are readable upon the elected species.** MPEP § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

Art Unit: 1639

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).



Art Unit: 1639

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

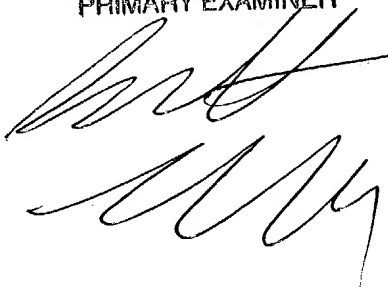
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.  
August 5, 2004

BENNETT CELSA  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'Bennett Celsa', written over the printed name and title.